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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,119

03/30/2006

Laure Cloarec-Blanchard

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05/11/2009

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KALAMAZOO, MI 49007

EXAMINER

OH, TAYLOR V

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

05/11/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/574,119	Applicant(s) CLOAREC-BLANCHARD ET AL.	
	Examiner Taylor Victor Oh	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Final Rejection

The Status of Claims

Claims 12-24 are pending.

Claims 12-24 are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claims 16-20,22 and 24 under 35 U.S.C. 112, second paragraph, has been withdrawn due to the modification of the claims in the amendment.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of Claim 23 under 35 U.S.C. 112, first paragraph, has been withdrawn due to the modification of the claims in the amendment.

Claim Rejections - 35 USC § 103

1. Applicants' argument filed 2/09/09 have been fully considered but they are not persuasive.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of Claims 12-22 under 35 U.S.C. 103(a) as being unpatentable over Ogletree et al (US 2003/0109543) in view of Lavielle et al (US 5,472,979).

The rejection of Claims 12-22 under 35 U.S.C. 103(a) as being unpatentable over Ogletree et al (US 2003/0109543) in view of Lavielle et al (US 5,472,979) has been maintained with reasons of record filed on 8/22/08.

Applicants' Argument

2. Applicants argue the following issues:
 - a. According the Dr. Laurence's Declaration, there was an important synergy for clopidogrel and compound (A) ,whereas there was not much synergy observed for clopidogrel and BAYu3405, which was replaced for ifetroban due to its unavailability in the commercial market and a difficulty in synthesizing the compound; therefore, the superior and unexpected effects associated with the claimed invention are not taught by the Ogletree et al (US 2003/0109543) in view of Lavielle et al.

First, regarding applicant's argument, the Examiner has noted applicants' argument. However, Lavielle et al expressly teaches a negative piece of information for using BAYu3405 in inhibiting platelet aggregation as shown below(see col. 10, lines 43-54):

The compounds of formula (I) possess advantageous pharmacological properties. In particular, they are capable of inhibiting platelet aggregation induced by U46619 (9,11-dideoxy-11 α ,9 α -epoxymethanoprostaglandin F₂ α), a TXA₂ receptor agonist, of inhibiting contractions brought about by U46619 on guinea pig trachea and of preventing in vivo bronchoconstrictions induced by U46619 in guinea pigs. In addition, the compounds inhibit the synthesis of TXA₂ in the blood of rabbits. The compounds of the invention possess markedly more intense pharmacological activities than those of a reference compound, BAY U3405 (Drug of the Future, 16(8), 701–705, 1991).

From this, unlike applicant's argument, it seems so reasonable that the skilled artisan in the art would not have been contemplated for combining clopidogrel with BAYu3405 for testing out their synergy. On the other hand, Ogletree et al expressly describes a composition based on an ADP-receptor inhibitor, such as clopidogrel and a thromboxane A₂ antagonist, useful for the treatment of cardiovascular diseases. Similarly, Lavielle et al does teach the application of

3-{6-[(4-Chlorophenylsulfonyl)amino
]-2-methyl-5,6,7,8-tetrahydronaphth-1-yl} propionic
acid, sodium salt

having markedly more

intense pharmacological activities than BAYu3405, a thromboxane A2 antagonist as an antithrombotic to cardiovascular diseases.

Therefore, it would have been obvious to the skilled artisan in the art to be motivated to incorporate the Lavielle et al's compound of thromboxane A2 antagonist as an alternative to BAYu3405 into the Ogletree et al composition. This is because both prior art disclose the composition for the same utility of the treatment of cardiovascular diseases and the skilled artisan in the art would expect such a combination to be feasible and successful as guidance (see col. 10, lines 43-54) shown in the prior art. Therefore, unlike applicants' argument, the combined prior art are still relevant to the claimed invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Taylor Victor Oh, MSD,LAC
Primary Examiner
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/Taylor Victor Oh/
Primary Examiner, Art Unit 1625
5/08/09